86450

N THE LEATED STATES PATENT AND TRADEMARK OFFICE

In Re U.S. Patent Application

Applicant:

Jeffrey L.C. Wright and

Jaroslav A. Kralovec

Serial No.:

10/070,181

Filed:

February 27, 2002

For: A Nutritional Supplement for Lowering Serum Triglyceride Cholesterol

Levels

I hereby certify that this correspondence is being deposited with the United Postal Service as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231, on March 20, 2002.

Gerald T. Shekleton Reg. No. 27,466

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. §1.97, a list of documents is disclosed on the attached Form PTO-1449 that may be material to the examination of this application. The cited references and International Search Report which are enclosed herewith.

Documents for which the supplied date of publication lists the year of publication without the month were published sufficiently earlier than the effective U.S. filing date and any foreign priority date, so that the particular month of publication is not in issue. Pursuant to §609 of the MPEP, it is understood that the month of publication is not required when the particular month of publication is not in issue.

No inferences should be drawn that the attached list represents a comprehensive investigation, or that any material disclosed is equivalent to the subject invention. In addition, none of the documents that have publication dates prior to the priority date of the above application anticipate the invention in this application.





Applicant avers that no art cited herein was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Statement.

The cited document(s) disclose numerous specific features. There has been no attempt to list each and every feature disclosed by each document. The Examiner is requested to review the document(s) and determine the extent of the materiality of the document disclosures with respect to the present invention.

The discussion of any art and the citation of any document(s) herein is not to be construed as an admission that the art or document disclosure is necessarily within the invention field of endeavor, that the art or document disclosure is necessarily prior in time to a particular date which may be relevant to the instant patent application, and/or that the art or document disclosure is otherwise necessarily prior art as defined by the patent law with respect to the instant invention and application.

Also, there is reserved the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosures of the art and document(s) recited herein, that may be cited by the Examiner in rejecting a claim in the instant patent application. The recitation herein of the art and document(s) is not to be construed as an assertion that more pertinent art could not possibly be in existence.

Respectfully submitted,

Gorald T

Registration No. 27,466

Theklob

Dated: March 19, 2002

22nd Floor

WELSH & KATZ, LTD.

120 South Riverside Plaza

Chicago, Illinois 60606 Telephone: 312/655-1500







Sheet 1 of 4 U.S. Department of Commerce Atty. Docket No. Serial No. (Rev. 5/92) Patent and Trademark Office Comparable to Form PTO-1449 86450 10/070,181 INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) Applicants Jeffrey L.C. Wright and Jaroslav A. Kralovec Group Filing Date: 02/27/2002 U.S. PATENT DOCUMENTS *Examiner Filing Date Class Subclass If Appropriate Initial Document Number Date Name David C.Mitchell 13/05/1986 4,588,717 14/01/1997 Eugster et al. 5,593,691 FOREIGN PATENT DOCUMENTS Translation Class Subclass Document Number Date Country Yes No 0 897 970 A1 24.02.1999 EP **ABS** 13/05/2000 **ABS** 1004594 EP EP ABS 0982315 01/03/2000 9806405 19/02/1998 PCT OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) International Search Report Rompp Chemie Lexicon. (1995) Georg Thieme Verlag, Germany, Table 2 on page 272 (English translation provided). Examiner Date Considered Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not *Examiner:

considered. Include copy of this form with next communication to applicant.

	Page 2 of 4
48	ty. Docket No. 86450
FOR APPLICANT'S INFORMATION MAR 2 6 2002	FFREY L.C. WRIGHT & Jaroslav A. Kralovec
DISCLOSURE STATEMENT	0/070,181 February 27, 2002
DADEMA	

REFERENCE DESIGNATION	U.S. PATENT DOCUMENTS
	U.U. I MILLIUI DOCUMENTO

EXAM. INIT.	DOCUMENT NUMBER					BER		DATE	NAME	CLASS	SUB CLASS	FIL.DATE IF APPROPRIATE	
	A1	5	5	0	2	0	4	5	26/03/96	MIETTINEN ET AL.	514	182	
	A2	5	8	9	2	0	6	8	06/04/99	HIGGINS, III	552	554	

FOREIGN PATENT DOCUMENTS

								1 010		141 DOCOMETATO				
												SUB	TRANSLATION	
			D	OCUM	ENT	NUME	BER		DATE	COUNTRY	CLASS	CLASS CLASS		NO
	B1	wo	92	1	9	6	4	0	12/11/92	PCT				
	B2	wo	96	1	0	0	3	3	04/O4/96	PCT				
	B3	ΕP	0	594	612	B1	1		03/05/91	Europe		-		
	B4	wo	97	3	5	5	9	4	02/10/97	PCT				
	B5	wo	98	0	6	7	1	4	19/02/98	PCT				
	B6	wo	98	1	8	4	2	9	07/05/98	PCT				ļ
	В7	EP	97	0	3	3	2	9	13/02/97	EUROPE				
	В8	wo	99	3	0	5	6	9	24/06/99	PCT				
	B9	wo	98	0	1	7	5	9	15/01/98	PCT				
	B10	1	3	3	7	5	4	8	14/11/95	CA				
1	1		i	1	•	1	1		.1	<u> </u>				

OTHER ART (including Author, Title, Date, Pertinent Pages, Etc.)

CI	Criqui M.H., "Triglycerides and Cardiovascular Disease, A Focus on Clinical Trials", European Heart Journal 19 (Supplement A); A36-A39
C2	Grundy, Scott M., "Small LDL, Atherogenic Dyslipidemia, and the Metabolic Syndrome", Circulation 95:1-4 (1997)
СЗ	Grundy, Scott M., "Hypertriglyceridemia, Atherogenic Dyslipidemia, and the Metabolic Syndrome", <i>American Journal of Cardiology</i> , 81(4A):18B-25B (1998)
C4	Gotto, Antonio M., Jr., "Triglyceride, The Forgotten Risk Factor", Circulation, 97:1027-1028 (1998)
CS	Jeppesen, Jorgen, et al., "Triglyceride Concentration and Ischemic Heart Disease, An Eight-Year Follow-up in the Copenhagen Male Study", Circulation 97:1029-1036 (1998)
C6	Guido Franceschini and Rodolfo Paoletti, "Pharmacological Control of Hypertriglyceridemia", Cardiovascular Drugs and Therapy, 1993:7:297-302 (1993)
C7	Eisenberg, Daniel, "The Importance of Lowering Cholesterol in Patients with Coronary Heart Disease", Clin. Cardiol. 21:81-84 (1998)
C8	"Randomised Trial of Cholesterol Lowering in 4444 Patients with Coronary Heart Disease: The Scandinavian Simvastatin Survival Study (4S)", <i>The Lancet</i> Vol. 344, Nov. 19, 1383-1389 (1994)
C9	Shepherd, James, et al., "Prevention of Coronary Heart Disease With Pravastatin in Men With Hypercholesterolemia", <i>The New England Journal of Medicine</i> ", Vol 333:1301-7 (1995)



20000	Sacks, Frank, M., et al., "The Effect of Pravastatin on Coronary Events After Myocardial Infarction in Patients with Average Cholesterol Levels", <i>The New England Journal of Medicine</i> , Vol. 335:1001-9 (1996)
C11	Heinemann, T., et al., "Mechanisms of Action of Plant Sterols on Inhibition of Cholesterol Absorption, Comparison of Sitosterol and Sitostanol", European Clinical Pharmacology, Vol 40: Suppl. 1:S59-S63 (1991)
C12	Ling, W.H., et al., "Dietary Phytosterols: A Review of Metabolism, Benefits and Side Effects", <i>Life Sciences</i> , Vol. 57, No. 3:195-296 (1995)
C13	Jones, Peter, J.H., et al., "Dietary Phytosterols as Cholesterol-Lowering Agents in Humans", Can. J. Physiol. Pharmacol. 75:217-227 (1997)
C14	Vanhanen, Hannu, T., et al., "Serum Cholesterol, Cholesterol Precursors, and Plant Sterols in Hypercholesterolemic Subjects with Different apoE Phenotypes During Dietary Sitostanol Ester Treatment", Journal of Lipid Reseach, 34:1535-1544 (1993)
C15	Miettinen, Tatu, A., et al., "Regulation of Cholesterol Metabolism by Dietary Plant Sterols", Current Opinion in Lipidology, 10:9-14 (1999)
C16	Heinemann, T., et al., "Effect of Low-Dose Sitostanol on Serum Cholesterol in Patients with Hypercholesterolemia", Arethrosclerosis 61: 219-223 (1986)
CI7	Vanhanen, H.T., et al., "Serum Levels, Absorption Efficiency, Faecal Elimination and Synthesis of Cholesterol During Increasing Doses of Dietary Sitostanol Esters in Hypercholesterolaemic Subjects", Clinical Science, 87:61-67 (1994)
C18	Leaf, Alexander, et al., "Medical Progress, Cardiovascular Effects of n-3 Fatty Acids", <i>The New England Journal of Medicine</i> , No. 9, 318:549-557 (1988)
C19	Mishkel, Gregory, J., et al., "Cardiovascular Effects of w-3 Polyunsaturated Fatty Acids (Fish Oils)", Bailliere's Clinical Haematology, No. 3, 3:625-649 (1990)
C20	Kinsella, John, E., et al., "Dietary n-3 Polyunsaturated Fatty Acids and Amelioration of Cardiovascular Disease: Possible Mechanisms ¹⁻³ , Am. J. Clin. Nutr., 52:1-28 (1990)
C21	Connor, Sonja, L., et al., "Are Fish Oils Beneficial in the Prevention and Treatment of Coronary Artery Disease?", Am. J. Clin. Nutr. 66 (Suppl.):1020S-31S (1997)
C22	Burr, M.L., et al., "Effects of Changes in Fat, Fish, and Fibre Intakes on Death and Myocardial Reinfarction: Diet and Reinfarction Trial (Dart), <i>The Lancet</i> , 757-761 (1989)

OTPE STATE OF THE PERSON OF TH



MAR 2 6 2002

Page 4 of 4

<i>\text{if}</i>	rage 4 01 4
10 To Market	von Shacky, Clemens, et al., "The Effect of Dietay ω-3 Fatty Acids on Coronary Atherosclerosis, A Randomized, Double-Blind, Placebo-Controlled Trial", Annals of Internal Medicine, 130:554-562 (1999)
C24	"Dietary Supplementation with n-3 Polyunsaturated Fatty Acids and Vitamin E after Myocardial Infarction: Results of the GISSI-Preventione Trial", <i>The Lancet</i> , 354:447-455 (1999)
C25	Harris, William, S., "Fish Oils and Plasma Lipid and Lipoprotein Metabolism in Humans: A Critical Review", <i>Journal of Lipid Research</i> , 30:785-807 (1989)
C26	Carey, Martin, C., et al., "Lipid Digestion and Absorption" Ann. Rev. Physiol. 45:651-77 (1983)
EXAMINER	DATE CONSIDERED

EXAMINER:

Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.